DRAFT DOCUMENT

This is a draft document. Comments should be sent to drugbenefitimpl@cms.hhs.gov. In commenting, please provide a contact name and phone number for any follow-up from CMS.

Please note, this draft solicitation is being issued to demonstrate the format and kind of information CMS intends to solicit in the application for a PDP contract. The solicitation reflects only the Notice of Proposed Rulemaking and will be changed to reflect the final policies announced in the final rule. The comment period for the NPRM has closed, and nothing in this draft is intended to reopen it. Therefore, please focus any comments on whether the solicitation adequately reflects the rules of the NPRM or the operational aspects of the solicitation. Comments that question or request modification to the substantive, underlying policies of the NPRM will not be considered.

Medicare Prescription Drug Benefit

Solicitation for Applications for Prescription Drug Plans (PDPs)

[DATE]

Summary Identification Form

Please complete each field in the table below and submit the information in this format with your application. You will be required to enter and maintain these data in the CMS Health Plan Management System (HPMS). Prompt entry and ongoing maintenance of these data in HPMS will facilitate the tracking of your application throughout the review process. In the even that you are awarded a contract, this information will also be used for frequent communications during implementation . Therefore, it is important that this information be accurate at all times.

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1. GENERAL INFORMATION

1.1 Purpose of Solicitation

The Centers for Medicare and Medicaid Services is seeking applications from qualified entities to enter into a contract to offer Medicare Prescription Drug Plans (PDPs) as described in the Medicare Prescription Drug Benefit Plan Final Rule (Federal Register, ***[INSERT DATE]***. Please submit your applications according to the process described in Section 2.0.

1.2 Background

The Medicare Prescription Drug Benefit program was established by section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and is codified in section 1860D of the Social Security Act (the Act). Section 101 of the MMA amended Title XVIII of the Social Security Act by redesignating Part D as Part E and inserting a new Part D, which establishes the Voluntary Prescription Drug Benefit Program (hereinafter referred to as "Part D").

1.3 Objectives and Structure

The new Part D benefit constitutes perhaps the most significant change to the Medicare program since its inception in 1965. The addition of outpatient drugs to the Medicare program reflects Congress' recognition of the fundamental change in recent years in how medical care is delivered in the U.S. It recognizes the vital role of prescription drugs in our health care delivery system, and the need to modernize Medicare to assure their availability to Medicare beneficiaries. Effective January 1, 2006, the Part D program establishes an optional prescription drug benefit for individuals who are entitled to Medicare Part A or enrolled in Part B.

In general, coverage for the new prescription drug benefit will be provided through private prescription drug plans (PDPs) that offer drug-only coverage, or through Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA-PD plans). PDPs must offer a basic drug benefit. MA-PD plans must offer either a basic benefit or broader coverage for no additional cost. If you meet the basic requirement, you may also offer supplemental benefits through enhanced alternative coverage for an additional premium.

Applicants, to offer either a PDP or MA-PD plan may offer national or regional plans. MA-PD plan applicants may also offer local plans. CMS has identified ***[INSERT NUMBER]*** regions in which PDPs or regional MA-PDs may be offered. The MMA requires that each region have at least two Medicare prescription drug plans from which to choose, and at least one of those must be a PDP. In regions where the required minimum number of plan choices is not available, the MMA requires CMS to contract with Fallback Plans. Fallback Plans must satisfy the same requirements as PDPs, but will receive reimbursement CMS on a cost rather than a risk basis. This solicitation is only for entities seeking to operate a PDP. Separate solicitations, also posted on the CMS web site, are for entities seeking to operate a local or regional MA-PD or Fallback plan.

You will have flexibility in terms of benefit design. This flexibility includes, but is not limited to, authority to establish a formulary that designates specific drugs that will be available within each therapeutic class of drugs, and the ability to have a cost-sharing structure other than the statutorily defined structure (subject to certain actuarial tests). The plans also may include supplemental drug coverage such that the total value of the coverage exceeds the value of basic prescription drug coverage.

1.4 Schedule

Application Review Process

Date	Milestone
Late January 2005	Posting of PDP, MA-PD, and Fallback Plan solicitations on CMS web site.
Late January 2005	Register for Pre-Application Conferences
Early February 2005	Pre-Application Conferences
Early February 2005	Submit notice of intent to apply to CMS.
Mid March 2005	Applications due.
May/June 2005	CMS sends Part D contract eligibility determination to Applicants, based on review of application. Applicant's bids must still be negotiated (see below).

Formulary Bid and Contracting Process

Date	Milestone
March 2005	CMS conducts detailed bid training for Applicants.
April 1, 2005	Applicants receive instructions to download Plan Benefit Package and Pricing Tool from the Health Plan

	Management System (HPMS). Applicants may begin submitting their bids.
April 18, 2005	Applicants submit formularies to CMS for review.
May 16, 2005	CMS provides preliminary approval of formularies.
June 6, 2005	Qualified Applicants submit bids to CMS for each of the Part D plans they propose to offer during 2006. Disapproved applicants requesting a reconsideration of CMS' determination must submit their bids on this date as well.
June 6, 2005 through July 24, 2005	Modifications to bids accepted only at the discretion of CMS.
July 2005	Training on submission of drug claims data to CMS.
July 24, 2005	CMS provides preliminary approval/disapproval of bids.
August 2, 2005	CMS publishes national average Part D premium.
September 2, 2005	CMS completes review and approval of bid data. CMS executes PDP sponsor contracts with qualified applicants who submit an acceptable bid.

Pre-Implementation and Implementation Process

Date	Milestone
Early Spring 2005	Begin bi-weekly Applicant/PDP sponsor technical support calls with CMS.
Early Spring 2005	Begin testing between PDP sponsors and CMS on information systems interfaces and data exchanges.
September 2005	Training on enrollment and payment.
November 15, 2005	Part D initial enrollment period begins for individuals who are first eligible to enroll in a Part D plan on or prior to January 31, 2006.
January 1, 2006	Medicare beneficiaries begin receiving drug benefits from Medicare Part D contractors.
May 15, 2006	Initial enrollment period ends for individuals who are first eligible to enroll in a Part D plan on or prior to January 31, 2006.

1.5 Revisions to Solicitation and Schedule

CMS reserves the right to amend or cancel this solicitation at any time. CMS also reserves the right to revise the Medicare Prescription Drug Benefit program implementation schedule, including the solicitation and bidding process timelines.

1.6 Summary of PDP Role and Responsibilities

Key aspects of each PDP shall include the ability to:

- Submit a formulary each year for CMS approval.

- Submit a PDP plan bid each year for CMS approval.

- Enroll all eligible Medicare beneficiaries who apply and reside within the PDP's approved service area. A sponsor must serve at least one entire region.

- Administer the Part D benefit, including providing coverage for drugs included in a CMS-approved formulary, administering appropriate deductibles and co-payments, managing the benefit using appropriate pharmacy benefit managerial tools, and operating effective oversight of that benefit.

- Provide access to negotiated prices on covered Part D drugs, with different strengths and doses available for those drugs, including a broad selection of generic drugs.

- Develop and administer an effective program to identify, investigate, and refer all instances of possible fraud and abuse of the Medicare Trust Fund.

- Ensure that records are maintained in accordance with CMS rules and regulations and that both records and facilities are available for CMS inspection and audit.

- Disclose the information necessary for CMS to oversee the program and ensure appropriate payments.

- Offer a contracted retail pharmacy network, providing convenient access to retail pharmacies.

- Process claims at the point of sale.

- Administer a coverage determinations, grievances, exceptions, and appeals process consistent with CMS requirements.

- Provide customer service to beneficiaries, including enrollment assistance, toll-free telephone customer service help, and education about the Part D benefit.

- Protect the privacy of beneficiaries and beneficiary-specific health information.

- Protect beneficiaries from identity theft.

- Develop education materials and conduct information and outreach activities consistent with CMS standards for completeness, appropriateness, and understandability.

- Develop and/or maintain systems to support enrollment, provide claims-based data to CMS, accept CMS payment (including subsidies for low-income beneficiaries), track true out-of-pocket costs, and support e-prescribing.

- Provide necessary data to CMS to support payment, oversight, and quality improvement activities.

1.7 Summary of CMS Role and Responsibilities

Approval Process

CMS will review all applications to determine whether the Applicant meets the qualifications we have established to enter into a Part D contract. This review will include a determination that the proposed formulary is not discriminatory as well as a determination of the appropriateness of the valuation of the proposed benefits and the actuarial equivalence of the offerings as necessary. Applicants judged qualified to enter into a Part D contract as a result of the review of responses to the solicitation that successfully negotiate a bid with CMS will be offered a Part D contract.

Part D Program Oversight

CMS will develop a Medicare Prescription Drug Benefit program monitoring system to ensure that the programs deliver good value through defined benefits and are compliant with program requirements. We will focus on several operational areas critical to the value of the benefit, including beneficiary access to and satisfaction with their Part D benefit and protection of the financial integrity of the program. Specific areas will include pharmacy access, adequacy and value of the benefit, benefit management, enrollment and disenrollment, information and outreach, program safeguard activities, customer service, confidentiality and security of enrollee information, and effectiveness of tracking true out-of-pocket expenses. (*NOTE: PDP sponsors, as covered entities under the Privacy Rule, are subject to investigation and penalties for findings of Privacy Rule violations as determined by the Department of Health and Human Services Office for Civil Rights and the Department of Justice.)*

We will monitor, through the analysis of data we collect from Part D sponsors, CMS contractors, and our own systems. The types of data we expect to collect from sponsors include: certain benefit data, claims data, cost data, benefit management data, marketing review information, and customer satisfaction and complaints data.

To monitor plan performance in the areas we have identified, we will: 1) engage a program safeguard contractor to conduct an on-site retrospective and prospective audits of PDP sponsors' bids; 2) conduct beneficiary satisfaction surveys and operate a complaints tracking system to monitor and manage complaints brought to our attention that are not satisfactorily resolved through PDP sponsors' grievance processes; and 3) conduct periodic site visits to verify PDP sponsor compliance with Part D program requirements. We will use information from all the specified sources to analyze the appropriateness and value of the benefit delivered, and to understand the opportunity for additional value and quality improvement. If any trends we identify indicate less than satisfactory performance, significant departures from the marketed Part D offering, or fraud or other violations of State and Federal laws, appropriate action will be taken

ranging from request for corrective action plans to all categories of sanctions consistent with 42 CFR 423.509 and Part 423, Subpart O. We also will make referrals if appropriate to the Services Office of the Inspector General, or to Federal and State authorities where violations of laws under the jurisdictions of these agencies is in question.

Education and Outreach

CMS is committed to educating Medicare beneficiaries about the Part D program beginning with the first open enrollment period in November 2005 and as part of ongoing education efforts thereafter. CMS plans to educate beneficiary and consumer groups, health care providers, States, and other interested groups about the Part D program. Among the topics to be discussed with these groups is the identification and reporting of possible fraud and/or abuse. CMS may also engage in other activities that publicize or otherwise educate beneficiaries about the program.

Marketing Guidelines and Review

CMS will develop information and outreach guidelines to be posted on the CMS web site as a separate document from this solicitation. Part D sponsors are required to adhere to these guidelines in developing their marketing materials and marketing strategy. We have retained a contractor to provide technical assistance in the development of these guidelines and review materials submitted by plans in accordance with statutory requirements. Under 42 CFR §423.50, PDP sponsors are required to submit materials to CMS 45 days in advance of their distribution. If CMS fails to act on the materials within 45 days, the materials are deemed approved.

Eligibility for the Low Income Subsidy Program

Low-income Medicare beneficiaries will receive full or partial subsidies of premiums and reductions in cost sharing under the Part D benefit. Certain groups of Medicare beneficiaries will automatically be eligible for the low-income subsidy program. These beneficiaries include full benefit dual eligible individuals, Medicare beneficiaries who are recipients of Supplemental Security Income benefits, and participants in Medicare Savings Programs. Beneficiaries who are low-income and who do not fall into one of the automatic subsidy eligibility groups will apply for a low-income subsidy and have their eligibility determined by either the states or the Social Security Administration (SSA). We will develop a database to track individuals who are automatically deemed subsidy-eligible or who are determined subsidy-eligible by states or SSA, and communicate the names and eligibility category of those individuals to plan sponsors as part of the enrollment files from the enrollment processing system described below.

General Enrollment Processing

CMS has developed a system to review an individual's eligibility for the Part D benefit. For individuals applying for enrollment in a Part D plan, we will review an individual's status as a Medicare beneficiary. We will track enrollments and ensure enrollment exclusivity. We will also track low-income subsidy status and auto-enrollments of low-

income subsidy beneficiaries into prescription drug plans. Finally, we will track disenrollments from Part D plans and will block new enrollments during any given year unless the enrollment occurs during the Annual Coordinated Election Period or a special election period is indicated.

Payment to PDPs

CMS will provide payment to PDP sponsors in the form of advance monthly payments (consisting of the PDP plan's standardized bid, risk adjusted for health status, minus the beneficiary monthly premium), reinsurance subsidies when incurred, and low-income subsidies. After the end of the payment year, CMS will reconcile the correct amounts of low-income subsidies and reinsurance amounts against the amount paid as a part of the prospective monthly payments. Risk sharing amounts (if applicable) will be determined after all other reconciliations have been completed.

2. INSTRUCTIONS

2.1 Overview and Technical Questions

There are three types of entities with which CMS will contract to operate Medicare prescription drug benefit plans: PDPs, MA-PDs, and Fallback Plans. This application is to be completed by those entities seeking contracts as PDPs. Because of the work they will have already done in applying for an MA plan contract, MA-PD applicants are required to complete the Part D section of the MA application. The Part D section will essentially be an abbreviated form of this PDP application. While the Fallback plan requirements are in many respects similar to those associated with PDPs, there are certain important differences created by the Federal Acquisition Regulation (FAR) procurement process required by the statute that justifies creating a separate application for entities seeking Fallback plan contracts.

2.2 Pre-Application Conferences

CMS will hold pre-application conferences on ***[INSERT DATES]*** for all interested applicants. Applicants must pre-register for a conference on-line at www.cms.hhs.gov under the Medicare Prescription Drug Benefit by ***[INSERT DATE]***. The purpose of these conferences is to give Applicants the opportunity to ask questions about this solicitation and the bid process as well as about pre-implementation activities such as information systems requirements related to the Medicare Prescription Drug Benefit program. Questions submitted to CMS through DrugBenefit@cms.hhs.gov by Noon on ***[INSERT DATE]*** will have priority for oral response by CMS during the conference. Questions submitted after this date and from the floor will be addressed orally as time permits.

2.3 Other Technical Support

CMS will post a summary of the questions and CMS responses on the CMS Web site at www.cms.hhs.gov . CMS will conduct bi-weekly technical support calls with applicants and CMS operational experts (e.g., enrollment, information systems, marketing, bidding, formulary design, coordination of benefits). We will answer only operational/technical questions – not questions/comments addressed to the underlying rationale or legal basis for substantive policies.

2.4 Notice of Intent to Apply

To assist CMS in planning for the review of applications and to ensure that potential applicants are notified of any additional guidance posted on the web, and for future correspondence, potential applicants should notify CMS of their intention to apply by 5:00 p.m. EST on ***[INSERT DATE]***. The notice should indicate that your organization is applying for a PDP sponsor contract and describe the service area in which you intend to offer a PDP plan(s). As part of the notice of intent submission, Applicants must complete a CMS Connectivity Request (necessary to conduct enrollment transactions) and a Health Plan Management System Access Request (necessary to input and update PDP sponsor information). Applicants should send a notice of their intent to apply (including the completed CMS Connectivity Request in Attachment A) by electronic mail to:

[INSERT CMS CONTACT INFORMATION]

Applicants seeking the approval of multiple Part D plans should submit only one notice of intent to apply. This intent to apply should indicate the applicant's primary contact and include the contact's:

- Direct telephone number;
- Fax number;
- E-mail address;
- Mailing address;
- Completed CMS Connectivity Request (available on the CMS web site); and
- Health Plan Management System access request (Attachment #)

Organizations that submit a notice of intent to apply will be assigned a CMS identification number that will be used to identify any materials submitted by the organization throughout the application and bid processes. Once they receive their HPMS user identification numbers, organizations will need to input the information requested in Appendix XX of this solicitation.

Please note that entities that submit notices of intent to apply are not obligated to submit an application to CMS. However, CMS will not consider an application for approval from an entity that has not submitted a timely notice of intent to apply.

2.5 Instructions and Format of Qualifications

In preparing your application in response to the prompts in Section 3.0 of this solicitation, please check "yes" or "no" in sections organized with that format. If a written response

is necessary to provide sufficiently comprehensive information to support the application, please repeat the question followed by your response. CMS will check your application for completeness shortly after its receipt. We will notify Applicants of any deficiencies and afford them the opportunity to amend their applications.

In many instances Applicants are directed to affirm that they will meet particular requirements by indicating "yes" next to a statement of a particular Part D program requirement. By providing such attestation, an Applicant is committing its organization to complying with the relevant requirements as of September 15, 2005, unless otherwise noted in Section 3. While PDP sponsors are not required to begin providing the Part D benefit until January 1, 2006, CMS has established this earlier compliance deadline to allow adequate time for sponsors to cure any operational deficiencies before beneficiaries become entitled to Part D services. As with all aspects of a PDP sponsor's operations under its contract with CMS, we may verify a sponsor's compliance with qualifications it attests it will meet, through on-site visits at the PDP sponsor's facilities as well as through other program monitoring techniques. Failure to meet the requirements attested to in the Applicant's response to this solicitation and failure to operate its Part D plan(s) consistent with the requirements of the applicable statutes, regulations, and the Part D contract may delay a PDP sponsor's marketing and enrollment activities or, if corrections cannot be made timely, disqualify it from participation in the Part D program.

An individual with legal authority to bind the Applicant shall sign and submit the certification found in Section 4.0.

CMS reserves the right to request clarifications or corrections to a submitted application. The Applicant must provide the requested information within 10 days of the CMS request.

This solicitation does not commit CMS to pay any cost for the preparation and submission of an application.

To assure that each CMS review panelist receives the application in the manner intended by the applicant (e.g., collated, tabulated, colorized), applicants should deliver one (1) original and three (3) copies of the written application. Additionally, responses (including supporting documents) to each of the following subsections of the application must be submitted on a separate CD to support review of the application by different CMS components: CD #1 - Section 3.1, Subsections 3.1.1 and 3.1.2; CD #2 - Section 3.1, Subsection 3.1.3; CD # 3 - Sections 3.1.4 and Section 3.11; CD # 4 Sections 3.3 and 3.4. All other Sections and subsections must be submitted on a separate CD – CD #5. The CDs must be provided with the original application response as well as each of the three copies (3). Each CD must be labeled with the Applicant's name, CMS identification number, and relevant subsection title.

All copies and the original application should be in 3-ring binders. Tab indexing should be used to identify all major sections of the application. Page size should be 8 1/2 by 11 inches and the pages should be numbered. Type size should not be less than 12 point with a space and a half between lines.

Failure to submit an application consistent with these instructions may delay its review by CMS.

Applications must be sent to:

Centers for Medicare & Medicaid Services (CMS)
Center for Beneficiary Choices
Attn: ***[INSERT CMS CONTACT]***
7500 Security Boulevard
Mail Stop C4-23-07
Baltimore, Maryland 21244-1850

CMS will not review applications submitted after 5:00 P.M. on ***[INSERT DEADLINE]***.

2.6 Submission Software Training

Applicants will use the CMS Health Plan Management System (HPMS) during both the application and bid processes. Applicants will be required to enter the information contained in Appendix XX and Appendix XX into HPMS in order to facilitate the review process.

In order to provide formulary information and prepare plan bids, applicants will use HPMS to define their plan structures and associated plan service areas and then download the Formulary, Plan Benefit Package (PBP), and Bid Pricing Tool (BPT) software. For each plan being offered, applicants will use the formulary and PBP software to describe the detailed structure of their Part D benefit and the BPT software to define their bid pricing information. The formulary must accurately crosswalk to the PBP. The combination of the PBP and BPT for a plan comprises a bid. CMS anticipates releasing the HPMS bid creation functionality, including the formulary, PBP, and BPT software, on April 1, 2005.

Once the formulary, PBP, and BPT software have been completed for each plan being offered, applicants will upload their bids to HPMS. Applicants will be required to upload their formularies approximately four weeks prior to the submission of their PBP and BPT.

CMS plans to release the formulary upload functionality on April X, 2005 *[NOTE: Placeholder date]*. Formularies are due to CMS on April 18, 2005. CMS anticipates releasing the PBP and BPT bid upload functionality on May 20, 2005. Applicants will be able to submit uploads to HPMS on their PBP or BPT one or more times between May 20, 2005 and the CY 2006 bid deadline of June 6, 2005. CMS will use the last successful upload as the official bid submission.

CMS will provide technical instructions and guidance upon release of the HPMS bid functionality as well as formulary, PBP, and BPT software. In addition, hands-on systems training will be available at the Bid Training in March 2005.

2.7 System and Data Testing with CMS

HPMS

PDP organizations will use HPMS to communicate with CMS in support of the application process, bid submission process, ongoing operations of the Part D program, and reporting and oversight activities. PDPs are required to secure access to HPMS in order to carry out these functions.

Applicants should reference Appendix G for instructions on establishing access to HPMS. CMS strongly recommends that applicants establish connectivity to HPMS no later than April 1, 2005. *[NOTE: This is a placeholder date.]* Establishing connectivity by this date will ensure that applicants have sufficient time to prepare and submit their formularies to HPMS by May 1, 2005 and their PBPs and BPTs by June 6, 2005.

Enrollment

PDPs will be required to establish connectivity to CMS via the AT&T Medicare Data Communications Network (MDCN). This secure network allows direct transmission of enrollment information to CMS for processing. CMS will communicate a beneficiary's eligibility for enrollment in a Part D plan as well as for a low-income subsidy. CMS will also determine whether a beneficiary must pay a late enrollment penalty. CMS will record the results of this processing and reply to the PDP. Monthly membership listings will be made available for reconciliation purposes. They will be downloaded using the MDCN connectivity. Similarly, PDPs will be required to report disenrollment information to CMS.

A test environment will be established to accept, process, and reply to PDP transmissions. In addition, Help Desk staff will be available to assist PDPs in this process and to trouble-shoot reported problems. Testing is expected to occur during the summer of 2005. Specific instructions will be provided prior to that time.

Payment – PDPs

Payments will be wired to sponsor accounts on the first business day of each month (or the last business day of the prior month if the first day of the month is not a business day). PDPs that enter into a contract with CMS must submit banking information so that payments can be received.

The monthly payment will include premiums that SSA is deducting from beneficiary Social Security payments as well as those premiums CMS is paying on behalf of low-income individuals. Reinsurance subsidies, when incurred, and low-income subsidies will also be included.

Monthly beneficiary-level payment reports will be available detailing the components of each payment for reconciliation purposes. Sponsor-level reports summarizing the monthly payment and any applicable adjustments will also be provided. PDPs will download these reports via their MDCN connectivity.

Test versions of these reports will be provided in late summer of 2005. Specific testing instructions will be provided at a later date.

2.8 Summary Instruction and Format for Bids

Each PDP and MA-PD Applicant must submit to CMS a bid for each prescription drug plan it intends to offer. Applicants using this solicitation may apply to offer full or limited risk plans. CMS will accept bids for limited risk plans only in those regions where there are no full risk plans offered. (Please note that Applicants that indicate in their applications that they intend to offer limited risk plans are not precluded from later submitting full risk bids.) Where there are no full or partial risk plans available to beneficiaries, CMS will contract with entities to offer fallback plans. Organizations interested in participating in the Part D program by offering a fallback plan must follow a separate application process described on the CMS web site. CMS will not accept a risk bid from any entity that also submits a bid for the same year as a fallback plan in any region. *[NOTE: Further discussion of rules for subcontractors submitting bids for both PDP and Fallback required.]* Applicants must submit their formularies to HPMS on April 18, 2005 and the PBPs and BPTs on or before June 6, 2005.

2.8.1 Format of Bids

Bid Submission Sections Due Prior to June 6, 2005

To facilitate the timely review of all the bid submissions, CMS expects to require Applicants to submit the portion of their bid related to formulary and covered drugs on April 18, 2005. CMS will review areas of each proposed drug plan formulary by tier and drug availability and evaluate each element against evidence-based standards such as National Treatment Guidelines. Outliers will be selected for further review of the formulary development process prior to CMS approval of the bid. CMS will make the review criteria and algorithms available to applicants well in advance of the date Applicants must submit this information to CMS. CMS will make reasonable efforts to inform Applicants of their outliers so that they may substantiate their offering. If such substantiation is not satisfactory to CMS, the Applicant will be given the opportunity to modify the formulary. CMS intends to complete as much of this work as possible (at least two weeks) before the June 6, 2005 PBP and BPT submissions so that any modification may be reflected in those documents.

Bid Submission Due June 6, 2005

The Applicant's bid will represent the expected monthly cost to be incurred by the Applicant for qualified prescription drug coverage in the approved service area for a Part D-eligible beneficiary with a national average risk profile equal to 1.0. The costs represented in each bid should be those for which the Applicant would be responsible. These costs would not include payments made by the plan enrollee for deductible, coinsurance, copayments, or payments for the difference between the plan's allowance and an out-of-network pharmacy's usual and customary charge. The bid will require the separate identification, calculation, and reporting of costs assumed to

be reimbursed by CMS through reinsurance. CMS requires that the bid represent a uniform benefit package based upon a uniform level of premium and cost sharing among all beneficiaries enrolled in the plan. That is, all enrollees in a given plan (MA-PD or PDP) would be subject to the same cost sharing structure and would be charged the same premium for benefits the Applicant chose to offer. The benefit packages submitted must be crosswalked appropriately from the formulary. Pursuant to 423.505(l)(4), the CEO, CFO, or a delegee with the authority to sign on behalf of one of these officer, and who reports directly to such officer, must certify, based on best information, and belief) that the information in the bid submission is and assumptions related to projected reinsurance and low-income cost sharing subsidies is accurate, complete, and truthful, and fully conforms to the requirements in section 423.265 of the regulations.

2.8.2 CMS Review of Bids

CMS will evaluate the bids based on four broad areas: 1) administrative costs, 2) aggregate costs, 3) benefit structure, and 4) plan management. CMS will evaluate the administrative costs for reasonableness in comparison to other bidders and in comparison to a PDP sponsor's other lines of business. CMS will also examine aggregate costs to determine whether the revenue requirements for qualified prescription drug coverage are reasonable and equitable. In addition, CMS will review the steps the PDP sponsor is taking to control costs, such as through various programs to encourage use of generic drugs. Finally, CMS will examine indicators concerning plan management, such as customer service.

CMS is also required to make certain that bids and plan designs meet statutory and regulatory requirements. We will conduct an actuarial analysis to determine whether the proposed benefit meets the standard of providing qualified prescription drug coverage. Also, CMS will review the structure of the premiums, deductibles, copayments, and coinsurance charged to beneficiaries and other features of the benefit plan design to ensure that it is not discriminatory.

2.8.3 Overview of Bid Negotiation

CMS expects to evaluate the reasonableness of bids submitted by PDP sponsors by means of an actuarial valuation analysis. This would require evaluating assumptions regarding the expected distribution of costs, including average utilization and cost by drug coverage tier, for example in the case of standard coverage – 1) those with no claims, 2) those with claims up to the deductible, 3) those with claims between the deductible and the initial coverage limit, 4) those with claims between the initial coverage limit and the catastrophic limit, and those with claims in excess of the catastrophic limit. We could test these assumptions for reasonableness through actuarial analysis and comparison to industry standards and other comparable bids. Bid negotiation could take the form of negotiating changes upward or downward in the utilization and cost per script assumptions underlying the bid's actuarial basis. If the overall bids are unjustifiably high, CMS would have the authority to negotiate the bids down to a level that is more in keeping with bids that a private market would

provide. We could exercise our authority to deny a bid if we do not believe that the bid and its underlying drug prices reflect market rates.

2.9 Standard Contract with PDPs

Successful Applicants will be deemed qualified to enter into a Part D contract with CMS to operate one or more Medicare prescription drug plans. Only after the qualified Applicant and CMS have reached agreement on the Applicant's bid submissions will the Applicant be asked to execute its Part D contract.

The Part D contract will be for an initial 16-month term (September 1, 2005 through December 31, 2006), renewable after the initial term for one-year periods at the end of each calendar year at the option of both CMS and the Applicant. The initial 16-month contract period is intended to ensure that PDP sponsors meet enrollment and marketing requirements prior to the January 1, 2006 start date of the first Part D benefit period. The text of the standard contract is included in Appendix XX.

2.10 Additional Information Available

To assist Applicants in preparing the retail pharmacy network portion of their applications, CMS will provide upon request data from the U.S. Census Bureau on Zip Code-level population density.

To assist Applicants in preparing their bids, CMS has made the following drug use and drug spending information available at http://www.cms.hhs.gov/pdps/ :

- Individual-level data from the Medicare Current Beneficiary Survey (MCBS);
- Continuance tables based on MCBS data;
- Medicaid data based on 48 states.
- State-level expenditure adjusters based on Federal retirees in a national plan; Medicaid drug expenditure data for most states; and
- A 5 percent Medicare sample with drug data from the MCBS imputed to each beneficiary in the 5 percent sample. [*NOTE: To be released before the end of 2004]*.

2.11 Protection of Confidential Information

Only information within a submitted application (or attachments thereto) that constitutes a trade secret, privileged or confidential information, (as such terms are interpreted under the Freedom of Information Act and applicable case law), and is clearly labeled as such by the Applicant, and which includes an explanation of how it meets one of the exceptions specified in 45 CFR Part 5, will be protected from release by CMS under 5 U.S.C. § 552(b)(4). Information not labeled as trade secret, privileged, or confidential or not including an explanation of why it meets one of the FOIA exceptions in 45 CFR Part 5 will not be withheld from release under 5 U.S.C. § 552(b)(4).

2.12 Contact for All Inquiries

CMS will accept inquiries about the application, including questions concerning the pre-application conference and the notice of intent to apply, through electronic mail. Please send all inquiries to DrugBenefit@cms.hhs.gov. Please keep in mind that we plan to address only operational or technical questions. Questions or comments on the rationale or legal basis for the underlying policies of the drug benefit will not be considered.

3. Application

Introductory Note*: This solicitation restates and clarifies the requirements for PDPs in Part 423 of 42 C.F.R. Although this solicitation does not discuss each and every requirement of Part 423, all Applicants and PDPs are bound by such regulations. Therefore, please attest that you will meet all applicable requirements of Part 423, 42 C.F.R. We also note that while we do not believe this solicitation conflicts in any way with the regulations stated in 42 C.F.R. Part 423; to the extent a conflict becomes apparent, an Applicant or PDP sponsor should bring such conflict to our attention. If a conflict is identified, as required by law, the regulations will supersede conflicting rules stated in this solicitation.*

Note on the Draft Nature of this Document*: Publication of the final solicitation will follow the publication of the final rule. This solicitation is draft; it is being issued to demonstrate the format and kind of information CMS intends to solicit. Throughout this solicitation are sections of qualifications that provide specific draft qualifications, while other sections simply refer to the Notice of Proposed Rule Making (NPRM). Generally speaking, this approach to providing draft qualifications reflects instances where the direction of subregulatory policy development is beginning to crystalize based on the existing NPRM, as we consider public comments on such. Where qualifications are limited to citations in the NPRM, we are either less certain about the direction of the NPRM based on the public comments we are considering, or the NPRM does not provide a clear direction. In either case, providing subregulatory guidance would suggest a specific direction that would not be in keeping with the NPRM. The final solicitation will have specific qualifications in all sections, and any of the presently drafted qualifications could change depending on the final outcome of the final rule in accordance with the Administrative Procedures Act .*

3.1 Applicant Licensure and Financial Stability

3.1.1 Management and Operations

Applicant must attest 'Yes' to each of the following qualifications to be approved for a PDP contract. Attest 'Yes' or 'No' to each of the following qualifications by placing a checkmark in the relevant column.	Yes	No
--Applicant is applying to operate as a PDP sponsor.		

--Applicant is non-governmental legal entity which agrees to abide by the terms of a Medicare Prescription Drug Plan contract with CMS. --Applicant is not applying to operate as a Fallback Plan and has not been included as a subcontractor to any Fallback Plan in any region. --Applicant has administrative and management arrangements that feature: + A policy-making body (e.g., board of directors) exercising oversight and control over the PDP sponsor's policies and personnel (e.g., human resources) to ensure that management actions are in the best interest of the organization and its enrollees; and + Personnel and systems sufficient for the PDP sponsor to organize, implement, control and evaluate financial and marketing activities, the furnishing of prescription drug services, the quality assurance, medical therapy management, and drug and drug utilization management programs, and the administrative aspects of the organization; and + An executive manager whose appointment and removal are under the control of the policy-making body; and + A fidelity bond or bonds, procured by the Applicant, in an amount fixed by its policymaking body, but not less than $100,000 per individual, covering each officer and employee entrusted with the handling of its funds; and + Insurance policies secured and maintained by the Applicant, and approved by CMS to insure the Applicant against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks. -- Applicant provides evidence of and maintains contracts or other legal arrangements between or among the entities combined to meet the criteria concerning pharmacy access, enrollment, claims processing, beneficiary appeals, marketing materials, call center, and tracking true out-of-pocket (TrOOP) costs. -- Applicant's network pharmacy contracts contain provisions governing: + Submitting claims to a real-time claims adjudication system; + Providing access to negotiated prices; and + Applying the correct coinsurance amount, including for individuals qualifying for the low-income subsidy. + Informing the Part D enrollee at the point of sale (or at the point of delivery for mail order drugs) of the difference in price, if there exists a lower-priced, generically equivalent drug.		

-- Identify your organization by providing the following information:
+ Full legal organization name;
+ Full address of your organization's headquarters office;

+ Type of ownership (proprietary, partnership, publicly-traded corporation, privately-held corporation);
+ Your organization's parent organization, if any;
+ State in which your organization is incorporated or otherwise organized to do business;
+ Federal taxpayer identification number;
+ Name and title of individual who will sign the Medicare PDP contract, if application and bid are successful; Please see 42 CFR §423.502(b). This person must be authorized to act for the entity.
+ Name and title of company's contact person who can answer questions regarding your organization's proposal, including telephone number, fax number, and e-mail address.
+ Headquarters address, names of Chief Executive Officer and Chief Financial Officer, and name and address of your organization's point of contact for the Medicare Prescription Drug Plan program.

[Insert Table XX]

-- Provide a brief summary of the history, structure and ownership of your organization. Include a chart showing the structure of ownership, subsidiaries, and business affiliations. The organizational chart should depict the placement of the Medicare PDP operations within your organization as well as the reporting structure within your organization. Per Table XX, identify each of the entities with which you will subcontract to meet the qualifications of the Medicare PDP sponsor. If more than one subcontractor has been engaged to meet a particular requirement in Table XX, identify each of the subcontractors within the relevant requirement column. The following information on each subcontractor must also be identified.
+ Full legal organization name;
+ Full address of organization's headquarters office;
+ Type of ownership (proprietary, partnership, publicly-traded corporation, privately-held corporation);
+ Organization's parent organization, if any;
+ State in which organization is incorporated or otherwise organized to do business;
+ Federal taxpayer identification number;
+ Name and title of individual who signs the contract with the PDP applicant. This person must be authorized to act for the entity.
+ Headquarters address, names of Chief Executive Officer and Chief Financial Officer.

[Insert Table XX]

-- Provide copies of executed contracts with each subcontractor identified in Table XX that:
+ Clearly identify the parties to the contract (or letter of agreement);
+ Describe the functions to be performed by the subcontractor, as well as any reporting requirements the subcontractor has to the Applicant;

+ Contain language clearly indicating that the subcontractor has agreed to participate in your Medicare Prescription Drug Benefit program (except for a network pharmacy if the existing contract would allow participation in this program), and flow down clauses requiring their activities be consistent and comply with the Applicant's contractual obligations as a PDP sponsor;
+ Contain language describing the services to be performed in a manner that encompasses the services required to support the Medicare Prescription Drug Benefit program;
+ Describe the payment the subcontractor will receive for performance under the contract, if applicable;
+ Are for a term of at least the first year of the program (i.e., January 1, 2006 through December 31, 2006);
+ Are signed by a representative of each party with legal authority to bind the entity;
+ Contain language obligating the subcontractor to abide by all applicable Federal laws, regulations, and CMS instructions;
+ Contain language obligating the subcontractor to abide by State and Federal privacy and security requirements, including the privacy and security provisions stated in the regulations for this program at 42 CFR §423.136;
+ Contain language ensuring that the subcontractor will make their books and other records available to HHS, the Comptroller General, or their designees for inspection and audit and that this right of inspection will continue for a period of 6 years from the final date of the contract period or the date of audit completion, whichever is later;
+ Contain language that the subcontractor will ensure that beneficiaries are not held liable for fees that are the responsibility of the PDP sponsor;
+ Contain language that if the Applicant, upon becoming a PDP sponsor, delegates an activity or responsibility to the subcontractor, that such activity or responsibility may be revoked if CMS or the PDP sponsor determines the subcontractor has not performed satisfactorily. The subcontract may include remedies in lieu of revocation to address this requirement;
+ Contain language specifying that the Applicant, upon becoming a PDP sponsor, will monitor the performance of the subcontractor on an ongoing basis; and
+ If the subcontractor will establish the pharmacy network or select pharmacies to be included in the network, contain language that the PDP sponsor retains the right to approve, suspend, or terminate any arrangement with a pharmacy.

-- For network pharmacy contracts, provide the unsigned terms and conditions for each type of contract and a listing of which pharmacies have signed which contract. Contracts should contain all of the required provisions described immediately above for contracts or letters of agreement with the Applicant's subcontractors. Contracts should also contain provisions requiring network pharmacies to comply with all applicable Federal and State laws (including anti-kickback statutes and licensure requirements). No signature pages need be submitted at his time, but each Applicant must make a complete file of such pages available for inspection upon CMS' request.

3.1.2 Experience and Capabilities

Applicant must attest 'Yes' to each of the following qualifications to be approved for a PDP contract. Attest 'Yes' or 'No' to each of the following qualifications by placing a checkmark in the relevant column.	Yes	No
-- Applicant and/or one of its subcontractors must currently operate a pharmacy benefit program that performs the following activities: + Adjudication and processing of pharmacy claims at the point of sale; + Negotiation with prescription drug manufacturers and others for rebates, discounts, or other price concessions on prescription drugs; + Administration and tracking of enrollees' drug benefits in real time; + Coordination with other drug benefit programs, including for example, Medicaid, state-sponsored prescription drug benefit programs, Medigap, or other insurance. + Operation of an enrollee grievance and appeals process; and + Customer service functionality, including experience serving seniors and persons with a disability. -- Experience in each of these areas has occurred in the United States.		

-- As part of the discussion of the experience described immediately above, please indicate the business volumes your organization has generated in operating your benefit by completing the following table. If the entity underwent significant change in 2004, or it expects in 2005 to have substantially different business volumes, please comment and provide 2005 projected volumes in addition to your business volumes for 2004.

2003 Business Volumes

(Pharmacy-Related Entities)

	Insured Pharmacy Benefits **(#1)**	
Metric for Calendar Year 2004	**Retail**	**Mail**
Covered lives (#2)		
Senior lives (if available)		
Claims processed or number of discounted prescriptions		
Drug spending managed		

#1 Exclusive of any prescription drug discount card programs.

#2 a) Covered lives are discrete individuals for whom there is verifiable information / documentation that, on audit, would demonstrate their enrollment in the insured benefits program through either hard copy signed agreements, payment of insurance premiums, or some comparable verification. Covered lives are not demonstrated or accounted for by hits on a Web site or number of prescriptions filled or for which a claim was processed. Nor are covered lives demonstrated by

counting signed agreements and multiplying by an average family size (if a **family** premium was paid, the "family" is 2 people, unless the organization can document additional family members are included).

b) To calculate covered lives, use most recent data. Applicants should pick a point in time within the previous 12 months and provide the number of unique lives. Please specify month for point in time used.

3.1.3 Licensure and Solvency

NOTE: Applicant can only be approved for contract if either Item #1 or Item #2 below is answered 'yes', and in the event Item #2 is 'yes' CMS approves the request and the applicant meets CMS solvency standards. Attest 'Yes' or 'No' to the following State licensure requirement.	Yes	No
-- Applicant is licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which the Applicant proposes to offer a PDP. -- If Applicant does not meet Requirement #1, then Applicant has completed and provided to CMS a State licensure waiver request found in Appendix XX for each state in which it is not licensed by seeks to operate a PDP. -- If Applicant has provided licensure waiver request to CMS, is it in this application? -- If Applicant has provided licensure waiver requests to CMS, has it been sent in advance of this application to[**X address in waiver request form]**		

Reply 'Yes' or 'No' to each of the following qualifications by placing a checkmark in the relevant column. Applicant must truthfully reply 'Yes' to each of the following solvency qualifications, if a licensure waiver is approved by CMS, in order to be approved for a PDP contract.	Yes	No
-- If CMS grants the Applicant a waiver of the licensure requirement, the Applicant meets the CMS-published financial solvency and capital adequacy requirements. -- Applicant maintains fidelity bonds, in an amount not less than $100,000 per individual, for each of your organizations' officers and employees entrusted with the handling of your organization's funds. -- Applicant maintains policies that insure the applicant against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks		

-- Provide a resume for your organization's executive manager.

-- If State licensure has been denied due to poor performance, unethical conduct, complaints, or State law violations, please submit a one-page summary of the corrective action plan with your application to assure CMS that these activities have been addressed and corrected.

-- Describe your organization's policy-making body that oversees your organization's policies and personnel. Include a discussion of the membership of this body, as well as how frequently it meets and to whom it reports.

-- Describe your staffing plan for the operation of your Part D benefit plan(s). In particular, discuss the number of staff assigned to the following activities:
+ Financial;
+ Marketing;
+ Furnishing of prescription drug services;
+ Quality assurance;
+ Medical therapy management; and
+ Drug utilization management.

3.1.4 Business Integrity

Reply 'Yes' or 'No' to each of the following qualifications by placing a checkmark in the relevant column. Applicant must truthfully reply 'Yes' to each of the following qualifications to be approved for a PDP contract.	Yes	No
-- Applicant or its related entities (including affiliated companies or subsidiaries, subcontractor staff, any member of its board of directors, any key management or executive staff, or any major shareholder of 5% or more) do not appear on the Office of the Inspector General's Exclusion List or the General Services Administration's Excluded Parties List. -- Applicant mitigates the risk of conflicts of interest presented by the organization's financial relationships. A financial relationship means: 1) a direct or indirect ownership or investment (including an option or non-vested interest) in any entity that exists through equity, debt, or other means and includes any indirect ownership or investment interest, no matter how many levels removed from a direct interest, or 2) a compensation arrangement with an entity. -- Applicant mitigates the risk of organizational conflicts of interest. Organizational conflicts arise where, because of other activities or relationships with other persons, a person is unable or potentially unable to render impartial assistance or advice to the Government, or the person's objectivity in performing the contract work is or might be otherwise impaired, or a person has an unfair competitive advantage. -- Applicant will provide financial and organizational conflict of interest reports annually to CMS, pursuant to instructions to be issued by CMS. -- Applicant will report annually to CMS all potential financial		

and/organizational conflicts of interest.		

-- State whether your organization (including any affiliated companies or subsidiaries) or any member of its board of directors, or any key management or executive staff, or any major shareholders (5% or more) have been convicted of fraud in any state or federal court or been excluded from a federal or state health care program, including Medicare, Medicaid, Children's Health Insurance Program (CHIP), Federal Employees Health Benefits Program (FEHB), or any private health care payor or health insurer within the last five years.

-- State whether any of the potential subcontractors or affiliates of your organization or any member of their board of directors, or any key management or executive staff, or any major shareholders (5% or more) have been convicted of fraud in any state or federal court or been excluded from a federal or state health care program, including Medicare, Medicaid, Children's Health Insurance Program (CHIP), Federal Employees Health Benefits Program (FEHB), or any private health care payor or health insurer within the last five years.

-- State whether, within the last five years, your organization and/or any of its subcontractors entered into a settlement agreement or corporate integrity agreement with the United States Department of Justice, DHHS, or the Office of Personnel Management or any other governmental agency related to any fraud or abuse issue involving federal or state funds. For each settlement agreement, if any are identified, please submit a one-page narrative summarizing the terms and conditions of the settlement agreement and/or corporate integrity agreement. Your organization should be prepared to provide a copy of the settlement agreement and/or the corporate integrity agreement upon CMS' request.

-- Indicate whether to the best of your knowledge, your organization and/or any of its subcontractors, currently or in the last five years, is under investigation by the U.S. Department of Justice, the DHHS Office of the Inspector General, the Office of Personnel Management, or any other governmental agency related to any fraud or abuse issue involving federal or state funds. If so, please submit a one-page narrative summarizing the nature of each allegation and investigation.

-- Provide a one-page financial conflict of interest mitigation strategy for your organization.

-- Indicate whether your organization has any potential organizational conflicts of interest, as defined by the Q #3 above. Provide a one-page mitigation strategy for any identified potential conflicts.

3.2 Benefit Design

3.2.1 Pharmacy and Therapeutics (P&T) Committee

Applicant agrees to comply with 42 CFR §423.120(b).

3.2.2 Utilization Management Standards

Applicant agrees to comply with 42 CFR §423.153(b).

3.2.3. Quality Assurance and Patient Safety

Applicant agrees to comply with 42 CFR §423.153(c).

3.2.4 Medication Therapy Management

Applicant agrees to comply with 42 CFR §423.153(d).

3.2.5 Electronic Prescription Program

Applicant agrees to comply with 42 CFR §423.159(a).

3.3 Service Area/Regions

Applicant agrees to comply with 42 CFR §423.112(a).

3.4 Pharmacy Network

Retail Pharmacy

-- Using the Geographic Information Systems (GIS) or similar software, demonstrate that the pharmacy access requirements in Section 423.120(a) are met. Urban areas are five-digit Zip Codes in which the population density is greater than 3,000 persons per square mile. Suburban areas are five-digit Zip Codes in which the population density is between 1,000 and 3,000 persons per square mile. Rural areas are five-digit Zip Codes in which the population density is less than 1,000 persons per square mile.

The demonstration of pharmacy access must be based on a computation using 100% of beneficiary counts by Zip Code (provided by CMS). Maps and tables must be generated with data for the pharmacy network under contract for the Part D benefit. [CMS will provide Census Bureau population density figures by Zip Code so that sponsors can identify which Zip Codes are urban, which are suburban, and which are rural.] Maps and tables generated by the mapping software must include aggregate urban, suburban, and rural ratios for the entire service area to be served by the PDP sponsor, as well as urban, suburban, and rural ratios for each region, state, county, and Zip Code included under the program.

-- Provide an electronic list of all retail pharmacy outlets included in the analysis, including full name of pharmacy, address (including Zip Code), and telephone number. Also indicate whether the pharmacy is currently under contract for the Part D program or simply in negotiations to enter into such a contract.

Insert Table XX

Out of Network Pharmacies

Reply 'Yes' or 'No' to each of the following qualifications by placing a checkmark in the relevant column. Applicant must truthfully reply 'Yes' to each of the following qualifications to be approved for a PDP contract.	Yes	No
-- Applicant assures that enrollees have adequate access to covered Part D drugs dispensed at out-of-network pharmacies when such enrollees cannot reasonably be expected to obtain such drugs at a network pharmacy. -- Applicant affirms that Applicant will develop policies and procedures governing beneficiaries access to out-of-network pharmacies in the cases of an enrollee medical emergency, travel, or portions of service area inadequately served by contracted pharmacy network.		

Mail Order Pharmacies

Applicants <u>may</u> offer a mail order option in addition to their contracted pharmacy network but mail order pharmacies do not count in assessing network adequacy. Mail order option <u>only</u> is precluded. Indicate 'Yes' or 'No' whether such pharmacy is offered.	Yes	No
-- Applicant is offering mail order pharmacy.		

-- If any of your PDP plans will include mail order pharmacies, complete Table XX:

+ Provide the mail order pharmacy name, address, phone number, business hours, and senior management point of contact.

Insert Table XX

Reply 'Yes' or 'No' to each of the following qualifications by placing a checkmark in the relevant column. Applicant must truthfully reply 'Yes' to each of the following qualifications to be approved for a PDP contract.	Yes	No
-- If Applicant is offering mail order, Applicant provides beneficiaries with access to a licensed pharmacist to answer questions should there be inquiries that require clinical attention.		

-- Provide a description of the service and its operations, including states in which the mail order pharmacy is licensed and the availability of a pharmacist to answer enrollee questions**.**

-- Indicate how you will monitor/conduct audits of mail order pharmacy services.

-- State when you expect your mail order service will be available to enrolled beneficiaries.

Specialty Pharmacy / Infusion Therapy; Long Term Care Pharmacy; I/T/U Pharmacy

Reply 'Yes' or 'No' to each of the following qualifications by placing a checkmark in the relevant column. Applicant must truthfully reply 'Yes' to each of the following qualifications to be approved for a PDP contract.	Yes	No
-- Applicant agrees to comply with Section 1860D-4(b)(1)(C)(iv) of the Social Security Act.		

3.5 Enrollment and Eligibility

Reply 'Yes' or 'No' to each of the following qualifications by placing a checkmark in the relevant column. Applicant must truthfully reply 'Yes' to each of the following qualifications to be approved for a PDP contract.	Yes	No
-- Applicant intends that all Medicare beneficiaries eligible for part D and residing in your service area will be permitted to enroll into your plan according to the guidelines provided by CMS during an applicable enrollment period. -- Applicant intends to limit enrollment in your Prescription Drug Plan to those eligible Medicare beneficiaries who reside within your service area. -- Applicant intends to accept auto-enrollments in accordance with procedures adopted by CMS for certain low-income beneficiaries who have failed to enroll in a Prescription Drug Plan of Medicare managed care plan offering qualified prescription drug coverage. -- Applicant intends not to enroll any beneficiary who is already enrolled in another Prescription Drug Plan or who is identified as a member of a Medicare managed care plan that offers Part D coverage (other than an MSA plan or private fee-for-service plan that does not provide qualified prescription drug coverage) except during election periods in which such an individual is permitted to do so. -- For the service area Applicant intends to cover, Applicant's plan can be ready to enroll beneficiaries by November 15, 2005 and to provide prescription drug coverage as described in materials submitted to CMS on January 1, 2006. -- Applicant will develop and operate a process for enrolling Medicare beneficiaries in your proposed Prescription Drug Plan that will include communicating eligibility determinations back to the applying		

beneficiary within the timeframe specified by CMS, communicating with beneficiaries regarding incomplete applications, and making enrollments effective according to the effective date policy associated with the enrollment period in which the enrollment is received in accordance with CMS guidance. -- Applicant will collect data elements specified by CMS for the purposes of enrolling an individual in a Prescription Drug Plan. -- Applicant has the capability to communicate mainframe to mainframe to exchange beneficiary eligibility data with CMS. -- Confirm that your organization will have the capability to accept and process disenrollment requests from beneficiaries, including communicating such requests to CMS and making the disenrollments effective according to the effective date policy associated with the enrollment period in which the disenrollment request is received. Confirm that such policies and procedures will address beneficiary requests for a Special Election Period and verification of the beneficiary's eligibility for a Special Election Period. -- Affirm that in the event of a contract termination, your process for notifying beneficiaries of the plan termination and alternatives for obtaining benefits under Part D will comply with the Part D regulations governing PDP contract termination and notice to beneficiaries. -- Applicant intends to develop and implement by November 15, 2005, policies and procedures (including appropriate notice and due process requirements) for optional involuntarily disenrollment as permitted by CMS. -- Applicant will provide enrollment cards by January 1, 2006, consistent with standards issued by the Secretary		

3.6 Grievances and Appeals

3.6.1 Grievances

Applicant agrees to comply with 42 CFR §423.564.

3.6.2 Appeals

Applicant agrees to comply with Subpart M, Part 423, 42 CFR.

3.7 Coordination of Benefits

Reply 'Yes' or 'No' to each of the following qualifications by placing a checkmark in the relevant column. Applicant must truthfully reply 'Yes' to each of the following qualifications to be approved for a PDP contract.	Yes	No
-- Applicant develops and operates system for collecting information from enrollees about enrollees' other health insurance, including whether such insurance covers outpatient prescription drugs. -- Applicant is familiar with Medicare Secondary Payer (MSP) rules and can identify which other payers are secondary to Medicare. -- Applicant permits SPAPs and other third party payers to coordinate benefits as required by the regulations in Subpart J, Part 423, 42 CFR. For example, an SPAP might pay the premium for supplemental benefits on behalf of a beneficiary.		

-- Describe your organization's system for collecting and updating enrollee information concerning their other health insurance.

-- Describe you organization's system for coordinating payment of claims by enrollees' other health insurance, including SPAPs. Include in your discussion how you coordinate claims payable by Medicare.

3.8 Tracking Out-of Pocket Costs (TrOOP)

Applicant agrees to comply with 42 CFR §423.464(f)(2).

3.9 Marketing/Beneficiary Communications

Applicant must attest 'Yes' to each of the following qualifications to be approved for a PDP contract. Attest 'Yes' or 'No' to each of the following qualifications by placing a checkmark in the relevant column.	Yes	No
-- Applicant agrees to make available to beneficiaries only those marketing materials that comply with CMS' marketing guidelines and have been reviewed and approved by CMS. Marketing materials include general audience materials about the program. NOTE: Under 42 CFR §423.50, PDP sponsors are required to submit materials to CMS 45 days in advance of their distribution. If CMS fails to act on the materials within 45 days, the materials are deemed approved. -- Applicant agrees to provide as described in the marketing guidelines, upon request of any beneficiary, information about the following PDP features:		

+ Enrollment procedures; + Potential for contract termination; + Benefits; + Pharmacy network; + Out-of-network pharmacy access; + Formulary; + Premiums; + Service area; + Utilization management procedures; + Frequency of beneficiary grievances and appeals; and + Financial condition of the PDP sponsor. -- Applicant maintains a toll-free customer service call center that is open during usual business hours and provides customer telephone service in compliance with usual business practices. This means that the applicant must comply with at least the following: + Call center operates from 0700 to 2400 ET Monday through Friday and 0900 through 2100 ET on weekends and holidays; + Eighty percent of all incoming customer calls are answered within 30 seconds; + The abandonment rate of all incoming customer calls does not exceed 5 percent; + Call center provides thorough information about the PDP benefit plan, including copayments, deductibles, and network pharmacies; + Call center features an explicit process for handling customer complaints; + Call center shall provide service to non-English speaking and hearing impaired beneficiaries.		

3.10 Provider Communications

Reply 'Yes' or 'No' to each of the following qualifications by placing a checkmark in the relevant column. Applicant must truthfully reply 'Yes' to each of the following qualifications to be approved for a PDP contract.	Yes	No
-- Applicant operates a toll-free call center dedicated to responding to inquiries from pharmacies regarding the Applicant's Medicare prescription drug benefit. Inquiries will concern such operational areas as claims processing questions, benefit coverage, claims submission, and claims payment.		

3.11 Control of Fraud, Abuse, and Waste

Applicant agrees to comply with 42 CFR §423.504(b)(4)(vi).

3.12 Reporting Requirements

Reply 'Yes' or 'No' to each of the following qualifications by placing a checkmark in the relevant column. Applicant must truthfully reply 'Yes' to each of the following qualifications to be approved for a PDP contract.	Yes	No

Business Transactions and Financial Requirements -- Applicant will report, consistent with 42 CFR §423.514(b), information related to significant business transactions within 120 days of the end of each fiscal year. This qualification includes combined financial statements, where required under 42 CFR §423.514(c). -- Applicant will notify CMS of any loans or other special arrangement made with contractors, subcontractors, and related entities. **Claims Data** -- The Applicant or the Applicant's representative, such as a Third Party Administrator (TPA), has data management processes and data systems capable of accomplishing the following: + Collection and submission of prescription drug claims information for Medicare enrollees for every Part D drug prescription in the format required by CMS. + Collection and submission of data in either an NCPDP or X12 format in a batch mode. Data to be collected will encompass quantity, type, and costs of pharmaceutical prescriptions filled for enrollees. The plan must link this information to Medicare beneficiary identification numbers (HIC#s). *NOTE: Currently, the NPRM requests comments with regard to weekly, monthly or quarterly data feeds.]* + Submission of data to CMS via the Medicare Data Communications Network (MDCN) *[INSERT REFERENCE TO CMS INSTRUCTION DOCUMENT]* + Performance of data edit and quality control procedures to ensure accurate and complete prescription drug data. + Correction of all data errors identified by CMS. + Collection of data for dates of service within the coverage period with a 3-month closeout window for the submission of remaining unreported claims data. + Provision of additional information for the purposes of reconciliation of risk factors, low income subsidy payments, reinsurance payments, and risk corridor as required by CMS. + Provision of documentation, as specified by CMS, to support the accuracy and completeness of data. Documentation will be provided to CMS in response to an audit based request. **Rebate Data** -- The applicant or the applicant's representative has accounting systems capable of accomplishing the following: + Production of financial reports to support rebate accounting. The rebate accounting must allow for step-down cost reporting in which rebates received at the aggregate level may be apportioned down to		

the level of plan enrollees. + Provision of documentation, as specified by CMS, to support the accuracy and completeness of data. Documentation will be provided to CMS in response to an audit-based request. **Other Data** -- The Applicant will provide through HPMS routine administrative reports as directed by CMS, on a variety of measures that concern plan performance such as utilization management, customer service, and grievances and appeals.		

3.13 Data Exchange Between PDP and CMS

Reply 'Yes' or 'No' to each of the following qualifications by placing a checkmark in the relevant column. Applicant must truthfully reply 'Yes' to each of the following qualifications to be approved for a PDP contract.	Yes	No
HPMS -- Applicant agrees to use HPMS to communicate with CMS in support of the application process, bid submission process, ongoing operations of the Part D program, and reporting and oversight activities. PDPs are required to secure access to HPMS in order to carry out these functions. -- Applicant establishes access to HPMS according to the instructions in Appendix XX. NOTE: CMS strongly recommends that applicants establish connectivity to HPMS no later than April 1, 2005. *[NOTE: This is a placeholder date.]* Establishing connectivity by this date will ensure that applicants have sufficient amount of time to prepare and submit plan bids to HPMS by June 6, 2005. ***Enrollment & Payment*** -- Applicant agrees to establish connectivity to CMS via the AT&T Medicare Data Communications Network (MDCN). -- Applicant agrees to provide a test environment to accept, process and reply to PDP transmissions.		

NOTES on Enrollment & Payment:

This secure network allows direct transmission of enrollment information to CMS for processing. CMS will determine a beneficiary's eligibility for enrollment in a Part D plan as well as communicate eligibility for a low-income subsidy. CMS will also determine whether a beneficiary must pay a late enrollment penalty. CMS will record the results of this processing and reply to the PDP. Monthly membership listings will be made available for reconciliation purposes. They will be downloaded using the MDCN connectivity. Similarly, PDPs will be required to report disenrollment information to CMS

In addition, Help desk staff will be available to assist PDPs in this process and to trouble-shoot reported problems. Testing is expected to occur during the summer of 2005. Specific instructions will be provided prior to that time.

Payments will be wired to sponsor accounts on the first business day of each month (or the last business day of the prior month if the first day of the month is not a business day). PDPs that enter into a contract with CMS must submit banking information so that payments can be received.

The monthly payment will include premiums that CMS is deducting from beneficiary benefits (e.g., Social Security) as well as those premiums CMS is paying on behalf of low-income individuals. Reinsurance subsidies, when incurred, and low-income subsidies will also be included. Payments for risk-sharing, if applicable, will be made after other reconciliations have been completed.

Monthly beneficiary-level payment reports will be available detailing the components of each payment for reconciliation purposes. Sponsor-level reports summarizing the monthly payment and any applicable adjustments will also be provided. PDPs will download these reports via their MDCN connectivity.

Test versions of these reports will be provided in late summer of 2005. Specific testing instructions will be provided at a later date.

3.14 Privacy

Reply 'Yes' or 'No' to each of the following qualifications by placing a checkmark in the relevant column. Applicant must truthfully reply 'Yes' to each of the following qualifications to be approved for a PDP contract.	Yes	No
-- Applicant agrees not to use the Social Security Number (SSN) on the enrollees' identification cards.		
-- Applicant agrees to comply with the Privacy Rule as it applies to business associates of CMS for the purposes of operating the low income subsidy portion of the Part D drug benefit.		
-- Applicant agrees to notify each beneficiary, prior to enrollment or at the time of enrollment, of expected uses and disclosures of the beneficiary's protected health information, as well as the beneficiary's		

rights and Applicant's duties with respect to such information. Such notice is provided in plain language containing sufficient detail to advise the beneficiary of the uses and disclosures permitted or required under applicable law. -- Applicant agrees to obtain written authorization for all uses and disclosures of protected health information not otherwise permitted under the Privacy Rule. Beneficiaries may authorize disclosure of their protected health information to a third party, such as their employer. -- Applicant agrees to ensure that all its agents and subcontractors comply with all the requirements of 45 CFR Parts 162 and 164 when performing functions on the Applicant's behalf. -- Applicant agrees to comply with the requirements applicable to covered entities in 45 CFR Part 160 relating to use of national identifiers. -- Applicant agrees to comply with any applicable standards, implementation specifications, and requirements in the Standards for Electronic Transactions under 45 CFR Parts 160 and 162 subparts I *et seq*.		

3.15 Security and Record Retention

Reply 'Yes' or 'No' to each of the following qualifications by placing a checkmark in the relevant column. Applicant must truthfully reply 'Yes' to each of the following qualifications to be approved for a PDP contract.	Yes	No
Security -- Applicant attests (by completing Attachment XX) that, as of the initial enrollment date, appropriate administrative, technical, and physical safeguards will be in place to protect the privacy of protected health information in accordance with 45 CFR §164.530(c), and that you will meet the standards, requirements, and implementation specifications as set forth in 45 CFR part 164, subpart C, the HIPAA Security Rule, prior to beginning enrollment of beneficiaries. If you are unable to provide this later attestation, provide your plan for coming into compliance with the specifications as set forth in the Security Rule. You are encouraged, but not required, to use the Information Security Program references as provided by the National Institute of Standards and Technology (NIST) (see Attachment XXX) in describing your efforts to implement reasonable security measures. **Record Retention** -- The Applicant agrees to maintain, for 6 years, books, records,		

documents, and other evidence of accounting procedures and practices consistent with 42 CFR §423.505(d).		

2) Complete and provide Attachment XX

3.16 Claims Processing

Reply 'Yes' or 'No' to each of the following qualifications by placing a checkmark in the relevant column. Applicant must truthfully reply 'Yes' to each of the following qualifications to be approved for a PDP contract.	Yes	No
-- Applicant develops and operates an on-line claims processing systems that operates in real time to ensure accurate and timely payment of all claims submitted by network pharmacies on behalf of Part D plan enrollees. System operates according to the following standards: + 98% response within 4 seconds. + 99% of all claims paid with no errors. + 99% system availability --Applicant develops and operates a paper claims processing system designed to pay claims submitted by non-network pharmacies on behalf of Part D plan enrollees. Applicant processes claims according to the following standards: +100% of claims requiring no intervention handled within 15 days. +100% of claims requiring intervention handled within 30 days. +99% of all claims paid with no errors. -- If mail order pharmacy is offered, Applicant mail order processing meets the following standards: + Two business day turnaround time for receipt of prescription for in-stock items with no intervention. + Three business day turnaround time for receipt of prescription for in-stock items with intervention. -- Your organization has developed and has available for CMS inspection a complete description of your claims adjudication system including: + Hardware and software + Operating system + MediSpan or First Data Bank database, including number of iterations saved + Number of sites processing claims + System volume in covered lives, including the number of transactions the system can support per day and per hour. -- Your organization has developed and will make available to CMS upon request policies and procedures that include the following: + A complete description and flow chart detailing the claims adjudication process for each:		

• Contracted network pharmacies • Non-network pharmacies • Paper claims • Batch-processed claims • Direct key claims by Plan + A complete description and flow chart of the claims data retrieval process for each: • Entire claims history file • Encounter data required by state mandates • Encounter data required by alternate funding sources • Out-of-pocket maximum/deductible files + A complete description of claim detail management, including: • The length of time that detailed claim information is maintained online • The data storage process after it is no longer online • The length of time that detailed claim information is stored when it is no longer online • The accessibility of this information for data capture purposes. + A description of how overpayment and underpayments are handled and recovery procedures. + A complete description of procedures surrounding disputed claims, including: • The steps that a network pharmacy must follow to dispute a claim reimbursement • The average amount of time needed to resolve a claims dispute • Turnaround time standards for dispute resolution. + A complete description of the process to place a stop payment at an enrollee or a group level so no benefits are transmitted even though the enrollee or group may be eligible on the date of the fill. -- Your organization will have a robust testing process that will identify and correct any plan configuration errors prior to implementation. -- Your organization will accept eligibility files and any prior claims data electronically in NCPDP format. -- Your organization can document the manner and extent to which you have tested benefit designs such as drug exclusions or quantity limitations and plan parameters such as copayments or benefit maximums.		

4. CERTIFICATION

I, the undersigned, certify to the following:

1) I have read the contents of the completed application and the information contained herein is true, correct, and complete. If I become aware that any information in this application is not true, correct, or complete, I agree to notify the Centers for Medicare & Medicaid Services (CMS) immediately and in writing.

2) I authorize CMS to verify the information contained herein. I agree to notify CMS in writing of any changes that may jeopardize my ability to meet the qualifications stated in this application prior to such change or within 30 days of the effective date of such change. I understand that such a change may result in termination of the approval.

3) I agree that if my program meets the minimum qualifications and is Medicare-approved, I will abide by the requirements contained in Section 3.0 of this Application and provide the services outlined in my application.

4) Neither I, nor any owner, director, officer, or employee of the [Applicant] or other organization on whose behalf I am signing this certification statement, or any contractor retained by the company or any of the aforementioned persons, currently is subject to sanction under the Medicare or Medicaid program, or debarred, suspended or excluded under any other Federal or state agency or program, or otherwise prohibited from providing services to CMS or other Federal Agency.

5) I understand that in accordance with 18 U.S.C. § 1001, any omission, misrepresentation or falsification of any information contained in this application or contained in any communication supplying information to CMS to complete or clarify this application may be punishable by criminal, civil, or other administrative actions including revocation of approval, fines, and/or imprisonment under Federal law.

6) I further certify that I am an authorized representative, officer, chief executive officer, or general partner of the business organization that is applying for the approval of a Medicare prescription drug benefit program.

_____	_____
Authorized Representative Name (printed)	Title
_____	_____
Authorized Representative Signature	Date (MM/DD/YY)

5. APPENDICES

Appendix XX

Data Element	Element Description and Values	Applicant Response
Organization Legal Entity Name	Provide the legal entity name for the organization submitting this application.	
Type of Medicare Prescription Drug Benefit Contract	Identify the following: PDP	PDP
CMS Drug Region(s) to be Served	If you are proposing to serve <u>all</u> CMS drug regions, indicate "National" in your response. If you are proposing to serve one or more, but not all, regions, indicate which of the following apply: Region 1 Region 2 Etc.	
Trade Name	Provide the trade name for your organization, if different than the legal entity name above.	
Organization Marketing Name	Provide an alternative name that your organization may be use for marketing purposes. This name cannot exceed 50 characters and must comply with section 1140 of the Social Security Act.	
Organization Website Address	Provide the website address for your organization.	
Corporate Mailing	Provide the following	

Data Element	Element Description and Values	Applicant Response
Address	components: Street Address Line 1 Street Address Line 2 (if necessary) City State Zip Code	
Corporate Phone Number	Provide your corporate phone number.	
Corporate Fax Number	Provide your corporate fax number.	
Name of Application Contact	Provide the name of your application contact person.	
Application Contact Mailing Address	Provide the following components: Street Address Line 1 Street Address Line 2 (if necessary) City State Zip Code	
Application Contact Phone Number	Provide the phone number for your application contact person.	
Application Contact Fax Number	Provide the fax number for your application contact person.	
Application Contact E-Mail Address	Provide the e-mail address for your application contact person.	

Data Element	Element Description and Values	Applicant Response
Name of Chief Executive Officer (CEO)	Provide the name of your CEO.	
CEO Mailing Address	Provide the following components: Street Address Line 1 Street Address Line 2 (if necessary) City State Zip Code	
CEO Phone Number	Provide the phone number for your CEO.	
CEO Fax Number	Provide the fax number for your CEO.	
CEO E-Mail Address	Provide the e-mail address for your CEO.	
Name of Chief Financial Officer (CFO)	Provide the name of your CFO.	
CFO Mailing Address	Provide the following components: Street Address Line 1 Street Address Line 2 (if necessary) City State Zip Code	
CFO Phone Number	Provide the phone number for your CFO.	

Data Element	Element Description and Values	Applicant Response
CFO Fax Number	Provide the fax number for your CFO.	
CFO E-Mail Address	Provide the e-mail address for your CFO.	
Name of Medicare Compliance Officer	Provide the name of your Medicare Compliance Officer.	
Medicare Compliance Officer Mailing Address	Provide the following components: Street Address Line 1 Street Address Line 2 (if necessary) City State Zip Code	
Medicare Compliance Officer Phone Number	Provide the phone number for your Medicare Compliance Officer.	
Medicare Compliance Officer Fax Number	Provide the fax number for your Medicare Compliance Officer.	
Medicare Compliance Officer E-Mail Address	Provide the e-mail address for your Medicare Compliance Officer.	

If the Applicant is planning to offer more than one PDP plan, then complete the following table. This table must crosswalk how requirements are the same or different based on

each plan offering. The material provided in Section 3 must be consistent with and substantiate the findings within this table.

[NOTE: PLACEHOLDER FOR TABLE]

APPENDIX XX

Accessing CMS Systems

HPMS

PDPs will be required to use HPMS to carry out various CMS functions, including the application process, bid submission process, ongoing operations of the Part D program, and reporting and oversight activities. PDPs will need the following to access HPMS: (1) Internet **or** Medicare Data Communications Network (MDCN) connectivity, (2) use of a Microsoft Internet Explorer web browser (version 5.1 or higher) with 128-bit encryption, and (3) a CMS-issued user ID and password with access rights to HPMS for each user within the PDP organization who will require such access.

PDPs should access the CMS website at http://www.cms.hhs.gov/mdcn/access.pdf to obtain the latest version of the "Application for Access to CMS Computer Systems" form. In addition to completing each section of the form, as appropriate, the PDP user should check "Contractor (non-Medicare)" in Section 2, write your PDP contract number(s) in Section 2b (if assigned by CMS at the time of submission), write "HPMS" on the first blank line in Section 3a, and indicate that you are a "PDP Applicant" in Section 4. It is **critical** that you include this comment in Section 4, so that CMS can process your request appropriately. You must also sign and date the back page and return it along with the form. Your request cannot be processed without this signature and date. The original, signed form (both pages) must be mailed to the following address:

Centers for Medicare & Medicaid Services
Attention: Don Freeburger
Mail Stop C4-14-21
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Please contact Don Freeburger at either 410-786-4586 or DFreeburger@cms.hhs.gov with any questions. CMS will provide you with additional technical instructions on accessing HPMS, including its website address, once your user ID has been processed.

Important Note for Current HPMS Users: If your organization already has HPMS access for other CMS functions, such as an MA organization or as a Drug Card Sponsor, you do not need to request new CMS user IDs, unless you need to do so for new PDP users at your organization. Once your new PDP organization is enumerated by CMS, you will need to provide CMS with the list of current user IDs that require access to the new PDP contract number in HPMS. CMS will provide all PDPs with those instructions at the time of contract enumeration.

Appendix XX

HIPAA Security Attestation Statement

(Date)

_____ (MA-PDP, PDP etc.) attests that, as of the initial enrollment date, appropriate administrative, technical and physical safeguards will be in place to protect the privacy of protected health information in accordance with 45 CFR §164.530(c), and that we will meet the standards, requirements and implementation specifications as set forth in 45 CFR part 164, subpart C, the HIPAA Security Rule, prior to beginning enrollment of beneficiaries.

_____

(Signature of Chief Information Officer)

Attachment XXX
HIPAA Security Compliance Plan
(Modified from HIPAA Security Rule Appendix A to Subpart C to Part 164[1]--Security Standards: Matrix)

Complete the chart below using this example

Standards	Sections	Implementation Specifications (R)= Required, (A)= Addressable		Project / Activity	Scheduled Completion
Security Awareness and Training	164.308(a)(5)	Security Reminders	(A)	**Perform gap analysis, develop awareness program**	**3Q CY 2005**
		Protection from Malicious Software	(A)		
		Log-in Monitoring	(A)		
		Password Management	(A)		

ADMINISTRATIVE SAFEGUARDS (see § 164.308)

Standards	Sections	Implementation Specifications (R)= Required, (A)= Addressable		Project / Activity	Scheduled Completion
Security Management Process	164.308(a)(1)	Risk Analysis	(R)		
		Risk Management	(R)		
		Sanction Policy	(R)		
		Information System Activity Review	(R)		
Assigned Security Responsibility	164.308(a)(2)		(R)		
Workforce Security	164.308(a)(3)	Authorization and/or Supervision	(A)		
		Workforce Clearance Procedure	(A)		
		Termination Procedures	(A)		
Information Access Management	164.308(a)(4)	Isolating Health care Clearinghouse Function	(R)		
		Access Authorization	(A)		
		Access Establishment and Modification	(A)		
Security Awareness and Training	164.308(a)(5)	Security Reminders	(A)		
		Protection from Malicious Software	(A)		
		Log-in Monitoring	(A)		
		Password Management	(A)		
Security Incident Procedures	164.308(a)(6)	Response and Reporting	(R)		
Contingency Plan	164.308(a)(7)	Data Backup Plan	(R)		
		Disaster Recovery Plan	(R)		
		Emergency Mode Operation Plan	(R)		
		Testing and Revision Procedure	(A)		
		Application and Data Criticality Analysis	(A)		
Evaluation	164.308(a)(8)		(R)		
Business Associate	164.308(b)(1)	Written Contract or Other Arrangement	(R)		

[1] 45 CFR parts 160, 162 and 164 Health Insurance Reform: Security Standards; Final Rule

Contracts and other Arrangement					

PHYSICAL SAFEGUARDS (see § 164.310)

Standards	Sections	Implementation Specifications (R)= Required, (A)= Addressable		Project	Scheduled Completion
Facility Access Controls	164.310(a)(1)	Contingency Operations	(A)		
		Facility Security Plan	(A)		
		Access Control and Validation Procedures	(A)		
		Maintenance Records	(A)		
Workstation Use	164.310(b)		(R)		
Workstation Security	164.310(c)		(R)		
Device and Media Controls	164.310(d)(1)	Disposal	(R)		
		Media Re-use	(R)		
		Accountability	(A)		
		Data Backup and Storage	(A)		

TECHNICAL SAFEGUARDS (see 164.312)

Standards	Sections	Implementation Specifications (R)= Required, (A)= Addressable		Project	Scheduled Completion
Access Control	164.312(a)(1)	Unique User Identification	(R)		
		Emergency Access Procedure	(R)		
		Automatic Logoff	(A)		
		Encryption and Decryption	(A)		
Audit Controls	164.312(b)		(R)		
Integrity	164.312(c)(1)	Mechanism to Authenticate Electronic Protected Health Information	(A)		
Person or Entity Authentication	164.312(d)		(R)		
Transmission Security	164.312(e)(1)	Integrity Controls	(A)		
		Encryption	(A)		